

SEP 17 2001

510(K) SUMMARY

EXHIBIT #1

K011059

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: \_\_\_\_\_

1. Submitter's Identification:

Radiant Innovation Inc.  
No. 40, Lane 19, Bade road  
Hsin-Chu City  
Taiwan, R.O.C.

Contact:

Mr. James Huang  
General Manager

Date Summary Prepared: 3/20/2001

2. Name of the Device:

Infrared Ear Thermometer, Models TH8 series

3. Predicate Device Information:

Braun ThermoScan Instant Thermometer, IRT3020, IRT3520, Braun, Ltd., K#983295, ThermoScan Inc.

Omron Gentle Temp MC-509, Omron Health Care, K#922344, Omron Health Care.

4. Device Description:

The Radiant Innovation Inc., Infrared Tympanic Thermometer, Models TH8 series are electronic thermometers using an infrared detector (thermopile detector) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces of the patient.

The Radiant Innovation Inc., Infrared Ear Thermometer, Models TH8 series, consist mainly of four parts: an IR detector with a built in ambient temperature sensor, a barrel, a LCD display, and the associated circuit.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Radiant Innovation, Incorporated  
C/O Ms. Susan D. Goldstein -Falk  
Official Correspondent  
MDI Consultants Incorporated  
55 Northern Boulevard, Suite 200  
Great Neck, New York 11021

Re: K011059

Trade/Device Name: Infrared Ear Thermometer, Model TH8 Series  
Regulation Number: 880.2910  
Regulation Name: Clinical Electronic Thermometer  
Regulatory Class: II  
Product Code: FLL  
Dated: August 3, 2001  
Received: August 7, 2001

Dear Ms. Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

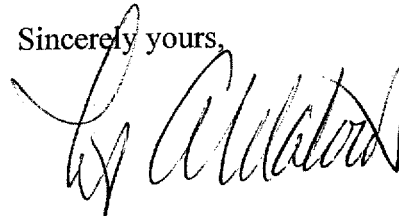
of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#EXHIBIT B

510(k) Number (if known): K011059

Device Name: Radiant Innovation Inc. Infrared Ear Thermometer, Models TH8 series

**Indications For Use:**

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒  
(Optional Format 1-2-96)

*Patricia Cusenza*

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K011059